



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0987]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review--Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0796. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for the Collection of Qualitative Data on Tobacco Products and
Communications

OMB Control Number 0910-0796--Extension

Under section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA is authorized to conduct educational and public information programs.

In conducting studies relating to the regulation and communications related to tobacco products, FDA will need to employ formative qualitative research, including focus groups, usability testing, and/or indepth interviews (IDIs) to assess knowledge and perceptions about tobacco-related topics with specific target audiences. The information collected will serve three major purposes. First, formative research will provide critical knowledge about target audiences. FDA must first understand people's knowledge and perceptions about tobacco-related topics prior to developing survey/research questions as well as stimuli for experimental studies. Second, by collecting communications usability information, FDA will be able to serve and respond to the ever-changing demands of consumers of tobacco products. Additionally, we will be able to determine the best way to present messages. Third, initial testing will allow FDA to assess consumer understanding of survey/research questions and study stimuli. Focus groups and/or IDIs with a sample of the target audience will allow FDA to refine the survey/research questions and study stimuli while they are still in the developmental stage. FDA will collect, and interpret information gathered through this generic clearance in order to: (1) better understand characteristics of the target audience--its perceptions, knowledge, attitudes, beliefs, and behaviors--and use these in the development of appropriate survey/research questions, study stimuli, or communications; (2) more efficiently and effectively design survey/research questions and study stimuli; and (3) more efficiently and effectively design experimental studies.

FDA is requesting approval of an extension of this generic clearance for collecting information using qualitative methods (i.e., individual interviews, small group discussions, and focus groups) for studies involving all tobacco products regulated by FDA. This information

will be used as a first step to explore concepts of interest and assist in the development of quantitative study proposals, complementing other important research efforts in the Agency. This information may also be used to help identify and develop communication messages, which may be used in education campaigns. Focus groups play an important role in gathering information because they allow for an indepth understanding of individuals' attitudes, beliefs, motivations, and feelings. Focus group research serves the narrowly defined need for direct and informal public opinion on a specific topic.

The number of respondents to be included in each new pretest may vary, depending on the nature of the material or message being tested and the target audience. Table 1 provides examples of the types of studies that may be administered and estimated burden levels during the 3-year period. Time to read, view, or listen to the message being tested is built into the "Hours per Response" figures. Our estimated burden for the information collection reflects an overall increase of 5,641 hours and a corresponding increase of 16,585 responses. We attribute this adjustment to the number of study responses used during the current approval and now estimated for the next 3 years.

In the *Federal Register* of September 29, 2020 (85 FR 60999), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments; however, only one was PRA-related.

(Comment) The comment expressed support for FDA's collection of qualitative research on tobacco products. The comment stated further that while FDA indicates that this research will meet the "narrowly defined need for direct and informal public opinion on a specific topic," the Agency has recently used this work for broader purposes, including informing the Proposed Rule for graphic health warnings."

(Response) FDA appreciates the support for conducting qualitative research on tobacco products. FDA disagrees with the comment suggesting that the Agency has used its qualitative generic collection for "broader purposes" than contemplated by the generic collection. Review

of a generic collection occurs in two stages: (1) a full PRA review of the generic clearance ICR, which includes the general approach and methodology, at least once every 3 years and (2) an expedited review of the individual collections that fall within the scope of the generic clearance. OMB reviewed the individual collection[s] that this comment cites and approved the collection, having determined that it was appropriately within the scope of the generic clearance.

FDA estimates the burden of this collection of information as follows:

Table 1.-- Estimated Annual Reporting Burden¹

Type of Interview	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
In-Person Individual IDIs	1,092	1	1,092	1	1,092
IDI Screener	1,800	1	1,800	0.083 (5 minutes)	150
Focus Group Screener	19,385	1	19,385	0.25 (15 minutes)	4,846
Focus Group Interviews	5,897	1	5,897	1.5	8,846
Total					14,934

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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